

application in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

The allowance of claims 1-6, 9, 10, and 18-21 is acknowledged by Applicants. The Examiner has made final the restriction requirement. In response thereto, Applicants have canceled without prejudice, the unelected claims, claims 36-46. Applicants reserve the right to file one or more divisional applications directed to the subject matter of the canceled claims.

Claims 11, 22, and 23 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner finds the recitation in claim 11 of "seed termination signal" as indefinite. In response to the rejection of claim 11, Applicants have amended the claim to recite "seed specific" termination signal. Page 16, line 25 of the specification refers to a "seed termination signal." It is respectfully submitted that such reference contains a typographical omission of the word "specific." On the same page of the specification, line 21, the corresponding promoter is referred to as a "seed-specific promoter." Applicants have amended the specification to read "seed-specific termination signal". As omission of the word "specific" is typographical in nature, the amendment to both the specification and Claim 11 does not introduce new matter to the application as originally filed.

In view of the amendment to claim 11, it is respectfully submitted that withdrawal of the rejection of claim 11 under 35 U.S.C. §112, second paragraph is warranted.

With respect to claim 22, the Examiner is of the opinion that the claim is indefinite since "it is unclear how a progeny would be regenerated from said plant cell." Office Action, page 2. In order to obviate the rejection, Applicants have amended claim 22 to recite "[a] plant which has been regenerated from the plant cell of claim 15." In addition, Applicants have added a new claim, claim 47, which recites "[p]rogeny of the plant of claim 22." Withdrawal of the rejection of claim 22 under 35 U.S.C. §112, second paragraph, is therefore respectfully requested.

Claims 7, 8 and 11 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey that at the time of filing the present application, the inventors were in possession of the invention. In particular, the Examiner's position is that "[t]he claims are drawn to vectors that comprise specified regulatory sequences, including a delta 6-desaturase, albumin, oleosin or helianthinin promoter, and a seed termination signal, which are not disclosed or described in the specification." Office Action of October 12, 1999, page 3.

In the first instance, Applicants direct the Examiner to page 15, lines 23-25, of the specification where in describing



sequence elements capable of effecting expression of a gene product, including promoters, it is disclosed that "[t]he upstream 5' untranslated region of the evening primrose Δ6-desaturase gene as depicted in Figure 10 may also be used." Thus, with respect to a delta 6-desaturase gene promoter, a disclosure is provided in the present application which evidences that the inventors were in fact in possession of the invention.

With respect to albumin, oleosin and helianthinin regulatory elements, such elements are described in the specification on page 17, by incorporation by reference. At least one of the named inventors on the present application, i.e., Dr. Terry Thomas, is a named co-inventor on all the applications which have been incorporated by reference in the present application. Thus, by virtue of the fact that Dr. Thomas is a co-inventor on the present application as well as those applications incorporated by reference, he most definitely was in possession of the claimed invention at the time of filing the present application.

Further in this regard, the applications which are incorporated by reference on page 17 of the present application have issued. Therefore, the disclosures therein which are incorporated in the present application are publically available. Thus, U.S. Application Serial No. 682,354 which is now abandoned, has matured into several U.S. Patents; U.S. Patent No. 5,869,325, U.S. Patent No. 5,824,865, and U.S. Patent No. 5,905,186. The '325 patent contains claims directed to seed-specific regulatory

A

regions from helianthinin genes. The `865 patent contains claims directed to ABA-responsive regulatory regions from helianthinin genes, and the `186 application contains claims directed to root-specific regulatory sequences from helianthinin genes.

In addition, U.S. Serial No. 08/831,570, directed to albumin regulatory elements and U.S. Serial No. 08/831,575, directed to oleosin regulatory elements, have issued as U.S. Patent Nos. 5,959,175 and 5,977,436, respectively. The cover pages of the aforementioned patents are provided herewith as Exhibit A. By this amendment, Applicants have amended the specification to include the patent numbers corresponding to the cited patent application serial numbers. Moreover, journal articles which correspond to the disclosures of the aforementioned patents are also publically available.

The function of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application relied upon, of the specific subject matter later claimed by him. In re Blaser, 556 F.2d 534, 194 U.S.P.Q. 122 (CCPA 1977). The proper test for sufficiency of support in a patent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." In re Kaslow, 707 F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983). Because co-inventor Terry Thomas is an inventor on those applications (now issued patents) listed in the specification on page 17 as well as the present application, one

A

skilled in the art would reasonably believe that Applicants were in possession of the subject matter recited in claims 7, 8, and 11 as of filing date of the present application. Withdrawal of the rejection of claims 7, 8, and 11 under 35 U.S.C. §112, first paragraph, is therefore warranted.

Claims 7, 8, 11-17, and 24-35 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly directed to non-enabled subject matter. Applicants traverse the rejection of claims 7, 8, and 11 and reassert the discussion in the preceding five paragraphs. Further, it is respectfully submitted that upon grant of the present application, a skilled artisan having the specification of same in hand, and knowledge of the literature extant, including the aforementioned patents and corresponding published papers, is able to make the expression vectors presently recited in claims 7, 8, and 11.

It is settled law that it is not necessary that every last detail of an invention be described, by working examples or otherwise. Ex parte Wolter 214 U.S.P.Q. 735 (Pat. Off. Bd. App. 1979). In addition, a patent need not teach and preferably omits, what is well known in the art." Hybritech Inc. v. Monoclonal Antibodies, Inc. 231 U.S.P.Q. 81 (Fed. Cir. 1986) (emphasis added). Withdrawal of the rejection of claims 7, 8, and 11 under 35 U.S.C. §112, first paragraph, is respectfully requested.

With respect to claims 12-17, Applicants have amended same to specifically recite bacterial, plant and fungal cells.

Withdrawal of the rejection of claims 12-17 under 35 U.S.C. §112, first paragraph, is therefore respectfully requested.

According to the Examiner, claims 24-35 are drawn to modifying the content of GLA in a cell or organism. Applicants respectfully submit that claims 24-31 are directed to methods of producing plants with increased gamma linolenic acid (GLA) content. The Examiner has also cited De Luca, V. (1993) *AgBiotech Information* 5(6):225N-229N, for the proposition that modifying metabolic pathways in a plant is unpredictable. The specification clearly teaches, however, that the $\Delta 6$ -desaturase gene may be used to transform plant cells to achieve altered fatty acid compositions as presently recited by the claims.

For example, methods of producing plants with increased GLA are described in the specification e.g., on page 20, line 20, to page 21, line 16 and Examples 12, 13 and 16. Moreover, Example 6 and Figure 4, Example 14, and Figures 8 and 9, demonstrate that the transformation of a plant with a gene encoding a $\Delta 6$ -desaturase gene is efficient in recovering a transformed plant with increased GLA levels.

Further in this regard, Applicants direct the Examiner to the second paragraph on page 228N of De Luca et al., wherein specific examples of alteration of lipid metabolic pathways using specific enzymes involved in fatty-acid biosynthesis are discussed in efficient and predictable terms. Withdrawal of the rejection of claims 24-31 under 35 U.S.C. §112, first paragraph, is therefore respectfully requested.

A

Claims 32-35, are presently amended to recite in relevant part, "[a] method of inducing or increasing production of gamma linolenic acid (GLA) in a bacteria or plant deficient or lacking in or producing low levels of GLA..." Applicants reserve the right to file one or more continuation applications directed to the subject matter canceled from claims 32-35. Withdrawal of the rejection of claims 32-35 under 35 U.S.C. §112, first paragraph, is therefore respectfully requested.

In view of the foregoing remarks and amendments, it is firmly believed that the subject case is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Ann R. Pokalsky
Registration No. 34,697

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343
ARP/lc

